

GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT BIOLOGICAL AGENTS AND TOXINS



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select biological agents and toxins were published by HHS (42 CFR 73; December 13, 2002) and by USDA (9 CFR 121 and 7 CFR 331; December 13, 2002).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities or facilities in complying with this legal obligation.

A registered entity or facility is required by law (42 CFR 73.17, 9 CFR 121 and 7 CFR 331) to contact CDC or APHIS immediately upon discovery of a theft or a release of a select biological agent and toxin not authorized under a federal act. The agency that the Responsible Official (RO) should contact is determined by the type of select biological agent or toxin involved in the incident. For HHS agents, the Responsible Official (RO) must contact CDC (telephone: 404-498-2255; facsimile: 404-498-2265). For USDA agents, the RO must contact APHIS (additional information for animal agents and toxins may be obtained by contacting APHIS by telephone: 301-734-3277, or facsimile: 301-734-3652). For HHS/USDA overlap agents, the RO must contact both APHIS and CDC at the numbers listed above (for USDA after hours call 1-866-994-5678). For plant agents or toxins the RO should contact APHIS (additional information may be obtained by telephone: 301-734-5519; facsimile: 301-734-8700). A listing of HHS select biological agents and toxins is available at http://www.acdc.gov/od/sap. A listing of USDA animal agents and toxins is available at http://www.aphis.usda.gov/vs/ncie/bta.html. The list of plant agents and toxins is available at http://www.aphis.usda.gov/ppq/permits.

The RO should contact the appropriate agency immediately upon discovery of loss, theft, or occurrence of release of the select biological agents and toxins to explain the circumstances. Notification of the proper agencies is important to assure that emergency response efforts, including medical intervention and follow-up surveillance of human or other animals potentially exposed by release of the select biological agents and toxins (s), are accomplished in a timely matter, if appropriate. For release of HHS select biological agents or toxins, the RO should also notify the local and State Health Department. For USDA agents, the State Veterinarian should be contacted; for restricted plant pathogens, the State Plant Regulatory Official should be notified. For HHS/USDA overlap agents both the State Veterinarian and State Health Departments should be notified. In the case of theft or loss, the local police and Department of Justice should be notified, as appropriate.

The theft, loss, or release of an HHS select biological agent or toxin must be reported immediately upon discovery to CDC by telephone (404-498-2255), facsimile (404-498-2265), or e-mail (lrsat@cdc.gov). The theft, loss, or release of a USDA select biological agent or toxin must be reported immediately upon discovery by calling APHIS at 1-866-994-5678 and following the instruction prompt. The theft, loss, or release of an HHS/USDA select biological agent or toxin must be reported immediately upon discovery to both CDC and APHIS. After the initial reporting by telephone, this form should be sent directly to CDC or APHIS, as appropriate, within 7 calendar days after the discovery of theft, loss, or release of select biological agents or toxins. This requirement is not satisfied by reporting the theft or significant loss in any other manner. The entity or facility is required to keep a copy of the notification form.

INSTRUCTIONS

RO must complete Sections 1 and 4. Section 2 should be completed for those entities for which a loss or theft has occurred. Section 3 should be completed for those entities that have a release of select biological agents or toxins. The RO must sign and date the form.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-3277. This guidance document and form are also available at http://www.aphis.usda.gov/vs/ncie and http://www.aphis.usda.gov/ppq/permits.

WHERE TO SEND THE COMPLETED FORM

For HHS agents, return completed forms to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

For USDA animal agents and toxins, return completed forms to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231.

For HHS/USDA overlap select biological agents and toxins, return forms to: both CDC and APHIS at the addresses provided.

For USDA plant agents and toxins, return completed forms to: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236



Entity name

Entity address (NOT a post office address)

REPORT OF THEFT, LOSS, OR RELEASE OF SELECT BIOLOGICAL AGENTS AND TOXINS



Zip Code

CDC#

State

Read all instructions carefully before completing the report. This report must be submitted by the Responsible Official. Answer all items completely and type or print in ink. The report must be signed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For USDA animal agents, submit document to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231. For HHS/USDA overlap agents submit the form to both CDC and APHIS. For USDA plant agents and toxins, return completed forms to: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236.

SECTION 1 - TO BE COMPLETED BY RESPONSIBLE OFFICIAL

City

Entity registration number

APHIS #

Responsible Official (RO)		Telephone		FAX	E-mail			
Address (NOT a post office address)			City		State	Zip Code		
8	SECTION 2 - TO BE COM SELECT	PLETED ONLY FOR BIOLOGICAL AGEI			THEFT OF			
IF LOS	ST ON SITE OR THEFT H	AS OCCURRED PR	OVIDE THE	FOLLOWING	INFORMATIO	N		
Provide a list of all missing	select biological agents and tox	kins (Complete Section 4)						
Date loss or theft noted	Date of last inventory	Name of principal investigator for laboratory with select biological agents and toxins						
aboratory building and room Name and telephone number of local police department notified								
Type of theft (Night break	Symbols o	Symbols or markings on containers (if any)						
	IF LOST OR STOLEN IN	TRANSIT PROVIDE	THE FOLL	OWING INFO	RMATION			
Provide a complete list of I	missing select biological agents	and toxins (Complete Sec	ction 4)					
Attach a copy of the Form	EA-101 that was associated wit	h this shipment						
Name of carrier		Airway	Airway bill number/tracking number					
Provide a detailed summa	ry of events (attach additional sh	neets if necessary):	'					
Package description (size,	shape, description of packaging	including number and ty	oe of inner pac	kages; attach ad	Iditional sheets if r	ecessary):		

PROVIDE THE FOLLOWING INFORMATION								
	SENDER INFORMATION		TON	RECIPIENT INFORMATION				
Name of person								
Name of entity/ facility								
CDC/APHIS registration number	CDC API		IIS	CDC	APHIS			
PHS/USDA import permit number	PHS	USD)A	PHS	USDA			
Date shipped					<u> </u>			
Telephone								
FAX								
CDC confirmation number from transfer form:			APHIS confirmatio	APHIS confirmation number from transfer form:				
Package with select biological agents	and toxins received by request	tor	Package with sele		ts and toxins was tampered with			
Other contents of package (e.g., coola	ant typoly		<u> </u>	<u> </u>				
Other contents of package (e.g., coola	пстуре).							
An internal review of laboratory proceed	•	tiated t	o prevent recurrence	es of loss of select	t biological agents and toxins at this			
entity/facility:	lo							
SECTION 3 – TO BE	COMPLETED ONLY FO AGEI		INTENTIONAL F	RELEASE OF	SELECT BIOLOGICAL			
Provide a list of all select biological agents and toxins released (Complete Section 4)								
Date of release Time of release	Date of release Time of release Name of principal investigator for laboratory with select biological agents and toxins							
Location of exposure or release (give	laboratory building, room, area	and su	urface or space invol	lved)				
Name and telephone number of local and or state health dept. notified Name and telephone number of emergency responders								
Biosafety level of laboratory where exposure occurred								
Names of person(s) involved in exposure (attach additional sheet if necessary) Number of animals exposed								
Injuries □ No □ Yes (If Yes, give names and occupations of individuals injured)								
Exposures No Yes (If Yes, give names and occupations of individuals exposed)								
Medical treatment was required □ No □ Yes (If Yes, explain)								
Provide a detailed summary of events (attach additional sheets if necessary; provide sufficient information so that the severity of the release can be								
understood):								
unuci stoody.								
Provide a summary of actions taken: ☐ Called ambulance ☐ Called fire ☐ Other (explain):	department ☐ Closed labor	ratory c	doors 🗖 Closed bui	ilding □ Consu	ulted MSDS or chemical database			

Provide a s	ummary of clean up actions	taken (attach additional sheet	s if necessary) :				
An internal entity:		ures and policies has been init	tiated b preve	nt recurrences of lo	ss of select biolo	gical agents a	and toxins at this	
Critity: 🗖	163							
		SECTION 4 – TO BE C	OMPLETE	D BY ALL APPL	ICANTS			
LIST OF SELECT BIOLOGICAL AGENTS AND TOXINS LOST, STOLEN OR UNINTENTIONALLY RELEASED								
	Select biological agents and toxins	Characterization of agent	Number of vials	Form (powder/liquid)	Vol or wt per vial (e.g., ml, mg, ng)	Total quantity	Concentration/vial (e.g., 10 ⁸ pfu/ml)	
Examples	Botulinum toxin	Neurotoxin A	50	liquid	5 ml	250 ml	1 mg/ml	
	Bacillus anthracis	Ames strain	25	liquid	1 ml	25 ml	10 ⁸ /ml	
	Ebola virus	Zaire	10	liquid	1 ml	10 ml	10 ⁷ pfu/ml	
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false stater 42 CFR 73 Signature of	ment on any part of this form , 9 CFR 121, or 7 CFR 331	ntained on this form is true and n, or its attachments, I may be may result in civil or criminal p	subject to crin enalties, inclu	ninal fines and/or im ding imprisonment.	nprisonment. I fu	rther understa	and that violations of	

Public reporting burden: Public reporting burden of providing this information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

CDC FORM 0.1316 (08/31/2003); APHIS FORM 2043 (08/31/2003)